



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0194]

Agency Information Collection Activities: Proposed Collection; Comment Request; Biosimilars User Fee Cover Sheet; Form FDA 3792

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning Form FDA 3792, entitled "Biosimilars User Fee Cover Sheet."

DATES: Submit written or electronic comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER ].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60 day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on:

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of

information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The March 23, 2010 Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include 351(k) applications in the definition of "human drug application" for the purposes of the prescription drug user fee provisions. The authority conferred by the FD&C Act's prescription drug user fee provisions expires in September, 2012. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for fiscal years 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012. If enacted into law, FDA's proposed biosimilar biological product user fee program would require FDA to assess and collect user fees for certain meetings concerning biosimilar biological product development (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Proposed Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form would provide a cross-reference of the fees submitted for a submission with the actual submission by using a unique number tracking system. The information collected would be used

by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

Respondents to this proposed collection of information would be manufacturers of biosimilar biological product candidates. Based on FDA's database system, there are an estimated 18 manufacturers that fall into this category. However, not all manufacturers will have submissions in a given year and some may have multiple submissions. FDA estimates nine annual responses that include the following: Six INDs or BPD meetings, two applications, and one supplement. The estimated hours per response are based on FDA's past experience with other submissions, and average 30 minutes.

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3792	9	1	9	0.5	4.5

<sup>1</sup>There are no capital costs or operating maintenance costs associated with this collection of information.

Dated: March 7, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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